C-3. Safety Guidelines - Animal Pathogens

I. Scope

The Institutional Biosafety Committee (IBC) Registration and Animal Study Proposal programs are applicable to all Principal Investigators (PIs) who conduct animal research at the NCI-Frederick where animals may harbor known or potential human pathogens. It also applies to any off-site investigator who conducts animal research at the NCI-Frederick or utilizes technical animal support services provided by the NCI-Frederick.

II. Purpose

The IBC Pathogen Registration, Institutional Animal Care and Use Committee (IACUC) Animal Study Proposal, and Laboratory Animal Science Program (LASP) Animal Health Monitoring Programs are intended to protect the health and safety of the NCI-Frederick employees, the public, the environment, and animal populations. The programs are designed to meet the requirements for the Institutional Biosafety Committee (IBC), the Institutional Animal Care and Use Committee (IACUC), the Guide for the Care and Use of Laboratory Animals, NIH Guidelines, Animal Welfare Assurance for the Office for Protection from Research Risks (OPRR) and accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACI).

III. Definitions

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACI) - Is the organization that reviews the animal care and use program, inspects and accredits laboratory animal facilities for compliance with the humane and safe use of laboratory animals.

Institutional Animal Care and Use Committee (IACUC) - Is a committee established by the Public Health Service Policy (Public Law 99-158) and the Animal Welfare Regulations (Public Law 99-198). The NCI-Frederick IACUC reviews and approves all Animal Study Proposals and maintains relevant documentation.

Institutional Biosafety Committee (IBC) – As defined by the NIH Guidelines for Research Involving Recombinant DNA Molecules, the NCI-Frederick Institutional Biosafety Committee (NCI-Frederick IBC) was established to provide local review and oversight of nearly all forms of research utilizing recombinant DNA. The NCI-Frederick IBC has also been charged to review research being conducted with pathogens, oncogenes, human materials, biological toxins, transgenic and/or

knock-out/in animals and other potentially infectious material that is being performed at or sponsored by the NCI-Frederick.

Office for the Protection from Research Risks (OPRR) - Responsible for the implementation of the Public Health Service Policy. It is the office within NIH responsible for reviewing and issuing Animal Welfare Assurances for all research involving the use of animals.

Zoonotic Agents - Disease producing organisms transmissible from animals to humans under natural conditions. Such a disease process is known as a zoonosis.

IV. Responsibilities

A. NCI-Frederick Management

1. Responsible for ensuring that all animal research studies are conducted in compliance with the provisions of the NIH guidelines and with the approval of the IACUC and the IBC (as applicable).

2. Establish and implement policies and procedures for the safe conduct of animal studies and ensure compliance with the NIH guidelines and recommendations of the IBC and IACUC.

3. Ensure appropriate training regarding the safe use of laboratory animals to relevant staff including PIs, technicians, and animal care personnel.

4. Detailed operational protocols for technical support, animal housing and occupational medical surveillance must be developed as a team in conjunction with relevant input from the animal facility manager, technical staff, the Environment, Health and Safety Program (EHS), Occupational Health Services (OHS), and the PI.

B. Principal Investigator (PI)

1. Animal studies with known human pathogens (including zoonotic agents) are expected to be presented by the investigator for conceptual approval to the Director, Laboratory Animal Sciences Program. If there is support and concurrence that the study can be conducted, formal approvals are required. The PI must submit a detailed; (1) Animal Study Proposal to the IACUC for review and

approval and; (2) IBC Registration Form for review and approval by the IBC.

C. Environment, Health, and Safety (EHS)

1. The Biological Safety Office (BSO) will assist requestors (PI, animal facility manager, technical staff as appropriate, and OHS) on safety issues related to the use of zoonotic agents and animal pathogens. Assistance in completion of relevant IBC registration documents is provided upon request.

2. All Animal Study Proposals are reviewed by EHS. Animal studies involving pathogenic materials or other biological hazards require a NCI-Frederick IBC registration form and must be reviewed and approved by the IBC.

3. The Occupational Health Services will establish and maintain medical surveillance programs for personnel actively engaged in animal studies, especially those that may involve occupational exposure to zoonotic agents.

D. Employee

1. Must follow relevant policies and procedures (i.e., SOPs) for the safe handling of animals with known or potential zoonotic agents.

2. Report to their supervisor and OHS any conditions of illness, immunosuppression, or chemotherapy.

V. Procedures

A. Animal Studies Introducing Known Human Pathogens

1. All procedures are conducted at the appropriate ASP and IBC biocontainment level as determined by the professional judgement of the BSO using the most current version of NIH/Centers for Disease Control and Prevention (CDC) guidelines (Biosafety in Microbiological and Biomedical Laboratories, 5th ed.) as minimal criteria.

2. The research and animal care personnel must utilize available engineering controls and must wear appropriate personal protective equipment, taking all precautions to avoid contact with potentially

infected material, in accordance with all applicable and approved SOPs.

3. Waste and used supplies from these animals must be bagged within the ventilated engineering control in which they are housed or manipulated, and the outside of the bags disinfected with a 10% chlorine bleach solution prior to being autoclaved.

4. All individuals who may come into contact with infected animals or potentially infected waste must notify OHS and be enrolled in an appropriate surveillance program.

B. Naturally-Occurring Animal Pathogens Potentially Harmful to Humans (Zoonotic Agents)

A number of microbial agents naturally occurring in animals are known to infect humans. Infected animals may appear perfectly healthy; therefore, personnel should at all times follow Standard Precautions, including using personal protective equipment when handling animals or entering laboratory animal facilities.

1. Non-Human Primates

At present, no live non-human primate are housed at the NCI-Frederick, however off-site OTS Contractor employees provide caretaking and medical care to the non-human primate colony at NIH-Bethesda.

Individuals working with non-human primates or tissues, blood, etc. of non-human primate's origin should be particularly cautious since biological similarities between these animals and humans make them a greater hazard. Risk of exposure can be reduced or eliminated by avoiding direct contact with the animal's waste, bodily secretions, tissues and blood. This can be accomplished by:

a. Wearing the proper personal protective equipment.

b. Using specialized animal housing such as negative pressure or isolation units.

c. Ensuring that all of the protective shielding is in place and the unit is operating according to manufacturer or EHS guidelines.

d. Adherence to proper disinfection and decontamination procedures.

e. Rapid notification to the supervisor/manager when there is an equipment failure.

f. Injuries involving body fluids or contaminated sharps from non-human primates are potentially very hazardous and must be reported immediately to one's supervisor and OHS. Treatment of the injury begins at the worksite as outlined in the OHS Guidelines and the Animal Exposure Surveillance Program.

g. The non-human primate care staff at NIH Bethesda has extensive protocols (in addition to the above) which must also be followed.

2. Rodents

a. Individuals who work with rodents and related species are also at risk of potential exposure to primary infectious agents.

b. At NCI-Frederick, rodents and related species, while routinely monitored for zoonotic and other infectious agents, must be handled with the same respect and precautions as if known to be infected.

c. The use of Standard Precautions and protective equipment are intended to protect the individual from exposure when implemented and used correctly.

C. Opportunistic Pathogens

1. The rodent populations at NCI-Frederick may harbor a number of opportunistic pathogens which, under certain circumstances, may cause disease in humans.

2. Individuals who are immunosuppressed by illness, chemotherapeutic agents, or other medical drugs may have an increased level of risk.

3. Individuals who may be at risk due to health status or suppressed immunity must inform their supervisor and be immediately evaluated by OHS.

D. Xenobiotic Transplants

1. The deliberate introduction of human cells or tissues into immunodeficient rodents, a process called xenobiotic transplantation, can pose a zoonotic hazard to persons contacting these animals. The IACUC has adapted USPHS recommended guidelines for the prevention and control of infectious diseases associated with xenotransplantation of human cells/tissue into animals. These requirements include:

(i) Registration of the proposed work with BOTH the IACUC and the IBC.

(ii) Use of engineering controls as appropriate to the pathogen risk.

VI. References

Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources/National Research Council)

Biosafety in Microbiological and Biomedical Laboratories, current version.